UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF OKLAHOMA

MISTY DAWN LONG and DARREN WAYNE LONG, **Plaintiffs,** **v.** **ETHICON, INC., and JOHNSON & JOHNSON,** **Defendants.**	**Case No. 20-CV-181-JFH-JFJ**

OPINION AND ORDER

This matter comes before the Court on the Motion for Partial Summary Judgment ("Motion") [Dkt. No. 25], and Memorandum of Law in Support [Dkt. No. 26], filed by Defendant Ethicon, Inc. ("Ethicon"). The case began as part of multidistrict litigation in the United States District Court for the Southern District of West Virginia. *In re Ethicon, Inc., Pelvic Repair System Prods. Liability Litig.*, No. 2:12-MD-02327 (S.D.W. Va.). In April 2020, the West Virginia Court ordered 51 of the multidistrict litigation's cases to be transferred to appropriate jurisdictions. Dkt. No. 34. This case was directed to be transferred to this Court. *Id.* The transfer was completed on May 1, 2020. Dkt. No. 46.

Ethicon filed the Motion and supporting brief in the West Virginia Court on October 17, 2018. Dkt. No. 25; Dkt. No. 26. These filings addressed nine (9) claims within the Complaint, including a failure to warn claim (Count III). *Id.* Plaintiffs, Misty Dawn Long and Darren Wayne Long (collectively "Plaintiffs"), filed a Response on October 25, 2018, responding solely to Ethicon's products liability failure to warn claim. Dkt. No. 27. Ethicon filed a Reply regarding the failure to warn claim on October 31, 2018. Dkt. No. 28. The parties stipulated to the dismissal

of the remaining eight (8) counts and confirmed that Plaintiffs' failure to warn claim is the only outstanding claim in the Motion. Dkt. No. 73.

For the reasons set forth below, the Court grants the Motion.

STANDARD

"Summary judgment is appropriate if the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to a judgment as a matter of law." *Jones v. Kodak Med. Assistance Plan*, 169 F.3d 1287, 1291 (10th Cir. 1999); Fed. R. Civ. P. 56(a). "A dispute is genuine when the evidence is such that a reasonable jury could return a verdict for the nonmoving party, and a fact is material when it might affect the outcome of the suit under the governing substantive law." *Bird v. W. Valley City*, 832 F.3d 1188, 1199 (10th Cir. 2016). Only material factual disputes preclude the entry of summary judgment. *Atl. Richfield Co. v. Farm Credit Bank of Wichita*, 226 F.3d 1138, 1148 (10th Cir. 2000).

The movant bears the initial burden to demonstrate the absence of a genuine issue of material fact and its entitlement to judgment as a matter of law. *Adler v. Wal-Mart Stores, Inc.*, 144 F.3d 664, 670-71 (10th Cir. 1998). If the movant carries this initial burden, "the burden shifts to the nonmovant to go beyond the pleadings and set forth specific facts that would be admissible in evidence in the event of a trial from which a rational trier of fact could find for the nonmovant." *Id.* at 671. If the nonmovant demonstrates a genuine dispute as to material facts, the Court views the facts in the light most favorable to him. *Ricci v. DeStefano*, 557 U.S. 557, 586 (2009).

UNDISPUTED MATERIAL FACTS[1]

Ethicon developed a medical device called the TVT-O: a "mid-urethral sling" made of polypropylene mesh implanted near a woman's bladder to reduce or prevent female stress urinary incontinence. The device provides support to the patient's bladder and reduces abdominal pressure on the pelvic area. Board-certified gynecologist Dr. Darla Lofgren performed surgery on Plaintiff Misty Long in May 2015, including implantation of a TVT-O device. Mrs. Long had numerous post-surgical complications and eventually had the device removed by a different gynecologist.

ANALYSIS

A manufacturer is liable under Oklahoma product liability law if a plaintiff proves: (1) the manufacturer's product was the cause of the plaintiff's injury; (2) the defect existed in the product at the time it left the manufacturer's control; and (3) the defect made the product unreasonably dangerous. *Kirkland v. Gen. Motors Corp.*, 521 P.2d 1353, 1363 (Okla. 1974). A manufacturer has a duty to warn consumers of "potential dangers which may occur from the use of [a] product when it is known or should be known that hazards exist." *McKee v. Moore*, 648 P.2d 21, 23 (Okla. 1982). "[E]ven if a product is faultlessly designed . . . it may be considered unreasonably unsafe or defective if it is placed in the hands of the ultimate consumer without adequate warnings of the dangers involved in its use." *Id.*

Oklahoma recognizes the "learned intermediary" doctrine in product liability cases related to medical devices or drugs. *Edwards v. Basel Pharms.*, 933 P.2d 298 (Okla. 1997); *McKee*, 648 P.2d at 24. The doctrine sets out that a medical product "manufacturer's duty is to warn [a plaintiff's] physician, who acts as a learned intermediary between the manufacturer and the

[1] Both parties' briefing is quite scant on factual detail, perhaps because the Motion was originally filed in the multidistrict litigation. The Court has drawn these facts from the record before it, particularly the deposition of Dr. Darla Lofgren filed as an exhibit to Plaintiffs' Response.

consumer," because the physician "is in the best position to evaluate the patient's needs, [to] assess the benefits and risks of a particular therapy, and to supervise its use." *McKee*, 648 P.2d at 24. It is a physician's duty "to exercise independent judgment, taking into account [] knowledge of the patient as well as [of] the product." *Edwards*, 933 P.2d at 300 (quoting *Wooderson v. Ortho Pharm. Corp.*, 681 P.2d 1038, 1052 (Kan. 1984)). "In the absence of FDA regulations to the contrary, the manufacturer has no obligation to warn a consumer if the prescribing physician has been adequately warned of any adverse side effects." *McKee*, 648 P.2d at 24.

A rebuttable presumption arises in failure to warn cases that an adequate warning would have been read and heeded. *Woulfe v. Eli Lilly & Co.*, 965 F. Supp. 1478, 1483 (E.D. Okla. 1997). In a case where the learned intermediary doctrine applies, the defendant "may rebut this presumption by establishing that although the prescribing physician would have 'read and heeded' the warning or additional information, this would not have changed the prescribing physician's course of treatment." *Eck v. Parke, Davis & Co.*, 256 F.3d 1013, 1019 (10th Cir. 2001) (applying Oklahoma law). If a defendant successfully rebuts the presumption, the burden shifts "rather heavily" back to the plaintiff. *Id.* "To submit the case to a jury, [the plaintiff] must either discredit the physician['s] testimony or call into question the substance of the testimony, or otherwise demonstrate that the alleged failure to warn was the proximate cause of their injuries." *Id.*

Plaintiffs do not specify—and it is unclear to the Court—what warning Plaintiffs believe was lacking regarding the TVT-O device. Nevertheless, the Court will apply the rebuttable presumption that an adequate warning would have been read and heeded. The burden thus falls to Ethicon to demonstrate that the treating physician, Dr. Lofgren, would not have changed her course of treatment had she known additional information about the TVT-O device.

The evidence before the Court unequivocally shows Dr. Lofgren was confident in her treating decision. Dr. Lofgren testified that in May 2015, when she performed surgery on Mrs. Long, she had done approximately 90 or more TVT-O surgeries. Dkt. No. 27-1 at 22:16-19. She still used the device at the time of her deposition in 2018 with results she described as "excellent" and "absolutely" an improvement to patients' quality of life. Dkt. No. 27-1 at 24-25. Dr. Lofgren testified she believed use of the TVT-O is within the standard of care for gynecology [Dkt. No. 27-1 at 38:14-17] and explained her reasons for using the device:

> One, I'm comfortable with it, and I think it's always important when you're placing something that it's the surgeon's comfort level and experience with having good results with it in the past. I use this device because it goes lateral. I don't have the injury into the bladder like you do with the retropubic . . . . [So] one, I'm comfortable with it. Two, I think it has less risk with it . . . .
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> [I]t changes women's lives. When you have incontinence and it affects your life with your family and your job and just the way you live every day, when patients come back and they've had a bladder sling placed in and they no longer leak urine, their lives have changed. That's the purpose of what we do is to help people . . . . With the mid-urethral sling, I'm comfortable with the placement, and I'm very happy with my results. And so I continue to use it.

Dkt. No. 27-1 at 16:25-17:15, 24:8-14, 22-24.

Dr. Lofgren testified repeatedly that her surgical decision-making process is based on her education and experience, not manufacturer product warnings. *See, e.g.,* Dkt. No. 27-1 at 27:19-25, 38:19-21, 69:17-70:9, 158:7-19. She described literature from manufacturers as "just supportive" [*id.* at 159:19-24] and said, "I don't go by the manufacturer. I go by my education when I go to choosing what patients are candidates" to receive the TVT-O device [*id.* at 124:8-10]. Dr. Lofgren said she relies on diagnostic imaging, an exam, and a thorough medical history to make her decision for each patient, "not [on] what Ethicon said." *Id.* at 123:7-10. In sum, Dr.

Lofgren stated: "I don't choose Ethicon because it's Ethicon. I choose Ethicon because I've had success with this device, and I've had a lot of patient success." *Id.* at 104:10-14.

While Dr. Lofgren said she would have wanted to know additional information about the TVT-O device, she did not testify that she would have changed her treatment decision based on this knowledge. Dkt. No. 27-1 at 102:8-22. Dr. Lofgren believed that "if there's a device that has supported data that says you shouldn't be placing it," the information would come through the medical education updates she received and the device would be taken out of the market. *Id.* at 124:15-23, 125:5-8. Even after questioning from Plaintiff's counsel regarding the allegedly undisclosed issues with the TVT-O device,[2] Dr. Lofgren testified that she believed Plaintiff was a good candidate for the TVT-O [*id.* at 120:17-19, 122:3-7, 123:11-14] and did not have any risk factors contraindicating the device [*id.* at 122:25-123:1]. Dr. Lofgren's testimony is sufficient to rebut the presumption that an additional warning from Ethicon would have changed her treating decision. The burden thus shifts "rather heavily" back to Plaintiffs. *Eck*, 256 F.3d at 1019.

Plaintiffs do not attempt to discredit Dr. Lofgren's testimony or call into question the substance of her testimony. Quite the opposite: they cite to it repeatedly for the proposition that Dr. Lofgren "reli[ed] on Ethicon to inform her of the risks she was unaware of through Ethicon's written materials." Dkt. No. 27 at 5. The Court finds that the uncontroverted evidence does not support this characterization. As discussed above, Dr. Lofgren repeatedly testified that it was her experience and education, not Ethicon's warnings, that guided her treatment decision. Plaintiffs

[2] Although the parties do not specifically brief what information was allegedly omitted from Ethicon's warnings, it is the Court's impression from their arguments and Dr. Lofgren's deposition transcript that the TVT-O device implanted in Mrs. Long allegedly had rough, abrasive edges that put it at risk of fraying, twisting, or moving around within the implantation area.

introduce no other evidence that Ethicon's alleged failure to warn was the proximate cause of their injuries. Summary judgment is proper.

IT IS THEREFORE ORDERED that the Motion for Partial Summary Judgment filed by Defendant Ethicon Inc. [Dkt. No. 25] is **GRANTED**.

Dated this 1st day of September 2021.

JOHN F. HEIL, III
UNITED STATES DISTRICT JUDGE